

Appl. No. 09/652,493
Amdt. Dated December 17, 2004
Reply to Office action of May 18, 2004

- c. providing a normal value for α -dystroglycan expression levels on cell surfaces; and
- d. comparing the detection levels of α -dystroglycan to said normal value,
whereby ~~the absence~~ a decrease in levels of α -dystroglycan on said cells of the
sample indicates a higher potential for tumorigenicity.

Claim 6 (Currently amended): The method of claim 5, wherein said detecting comprises:

- a. adding to said sample a monoclonal antibody specific for α -dystroglycan,
and
- b. measuring the amount of labeled α -dystroglycan detected.

Claim 7 (Original): The method of claim 5, wherein said cells are human mammary epithelial cells.

Claim 8 (Currently amended): The method of claim 5, wherein the step of providing a normal value comprises measuring ~~said detecting comprises measurement of the amount of α -dystroglycan relative to the amount of β -dystroglycan on the surface of said cells,~~
wherein a relative decrease in the ratio of α -dystroglycan to β -dystroglycan indicates α -dystroglycan shedding and higher potential tumorigenicity.

Claims 9 – 21 (Canceled).

⁹
Claim 22 (Currently amended): A method of determining the likelihood that a patient has a tumor, by assaying proteolysed α -dystroglycan fragments ~~shed from a cell into blood in~~
patient serum, said method comprising the steps of:

Appl. No. 09/652,493
Amdt. Dated December 17, 2004
Reply to Office action of May 18, 2004

- a. contacting a serum sample to be assayed with a labeled antibody specific for an α -dystroglycan fragment, and
- b. assaying the amount of bound label,

~~whereby wherein~~ said α -dystroglycan fragments bound to said labeled antibody are is positively correlated with existence of a tumor cell growth in the patient.

10
Claim 23 (Currently amended): The method of Claim 22, wherein the α -dystroglycan fragment is an a fragment of approximately 120 kD fragment.

11
Claim 24 (Currently amended): The method of Claim 22, wherein the α -dystroglycan fragment is an a fragment of approximately 60 kD fragment.

Claims 25 – 28 (Canceled).

12
Claim 29 (Currently amended): The method of claim 22, wherein said tumor cell is an epithelial cell tumor.

13
Claim 30 (Currently amended): The method of claim 29, wherein said epithelial cell tumor is a breast epithelial cell tumor.